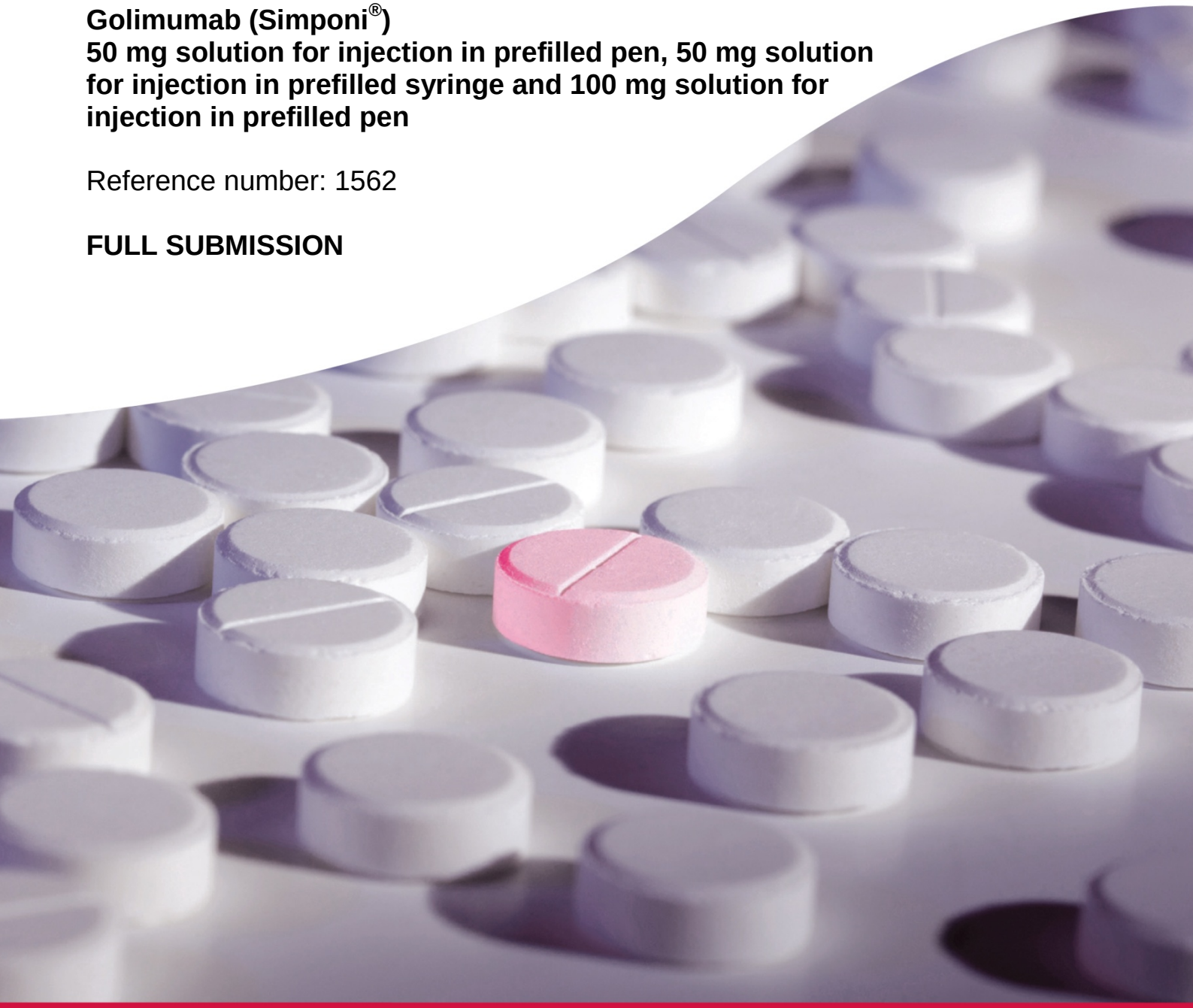
All Wales Therapeutics and Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

AWMSG SECRETARIAT ASSESSMENT REPORT

Golimumab (Simponi®) 50 mg solution for injection in prefilled pen, 50 mg solution for injection in prefilled syringe and 100 mg solution for injection in prefilled pen

Reference number: 1562

FULL SUBMISSION



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AWMSG Secretariat Assessment Report
Golimumab (Simponi®) 50 mg solution for injection in prefilled pen, 50 mg solution for injection in prefilled syringe and 100 mg solution for injection in prefilled pen

This assessment report is based on evidence submitted by Merck Sharp & Dohme Ltd on 25 February 2016[1].

1.0 PRODUCT DETAILS

Licensed indication under consideration	Golimumab (Simponi®) for the treatment of adults with severe, active non radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). Refer to the Summary of Product Characteristics (SPC) for the full licensed indication[2,3].
Dosing	The recommended dose of golimumab (Simponi®) for patients with nr-axSpA is 50 mg via subcutaneous injection once a month, administered on the same date each month. Clinical response is usually achieved within 12 to 14 weeks of treatment; continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. For patients with a body weight greater than 100 kg who do not achieve an adequate clinical response within 12 to 14 weeks of treatment, a dose increase to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse drug reactions. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after receiving 3 to 4 additional doses of 100 mg. Refer to the SPC for further information[2,3].
Marketing authorisation date	22 June 2015[4] (licensed for the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis on 1 October 2009 and ulcerative colitis on 19 September 2013; see SPC for full licensed indication[2,3]).

2.0 DECISION CONTEXT

2.1 Background

Axial spondyloarthritis (axSpA) is a chronic inflammatory condition affecting the axial skeleton. It can be classified into two subgroups: ankylosing spondylitis (AS; inflammation of the sacroiliac joint at the base of the spine [sacroiliitis] followed by inflammation rising along the spine) and non radiographic axSpA (nr-axSpA; axSpA without radiographic evidence of AS)[5,6]. Patients suffer from back pain, spinal stiffness and decreased mobility[6]. The use of magnetic resonance imaging (MRI) and/or

increased levels of C-reactive protein (CRP) signify the presence of inflammation in the axial skeleton of nr-axSpA patients, in the absence of radiographic changes[5].

Clinical guidelines recommend nonsteroidal anti-inflammatory drugs (NSAIDs) first-line for symptomatic control in patients with nr-axSPA[5]. For non-responders or for patients who cannot tolerate NSAIDs, these guidelines recommend treatment with adalimumab, certolizumab pegol and etanercept. An adequate response to treatment is defined as a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI [see Glossary]) score to 50% of the pre-treatment value or by a score of 2 or more, and a reduction in the spinal pain analogue scale (VAS) by 2 cm or more[5]. Golimumab, adalimumab, certolizumab pegol and etanercept are inhibitors of the pro-inflammatory cytokine, tumour necrosis factor (TNF) alpha[6].

2.2 Comparators

The comparators included in the company submission were:

- Adalimumab (Humira®)
- Certolizumab pegol (Cimzia®)
- Etanercept (Enbrel®).

2.3 Guidance and related advice

- National Institute for Health and Care Excellence (NICE). Technology Appraisal (TA) 383. TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (2016)[5].
- The British Society for Rheumatology (BSR). Biologics for the treatment of axial spondyloarthritis (including ankylosing spondylitis) (2015)[7].
- Assessment of SpondyloArthritis international Society (ASAS). 2010 update of the ASAS/European League against Rheumatism recommendations for the management of ankylosing spondylitis (2011)[8].
- ASAS. 2010 update of the ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis (2011)[9].

AWMSG has previously issued recommendations for the use of adalimumab (Humira®)[10] and certolizumab pegol (Cimzia®)[11].

3.0 SUMMARY OF EVIDENCE ON CLINICAL EFFECTIVENESS

The company submission included details of one phase III study (GO-AHEAD) comparing golimumab to placebo, as well as a systematic review and network meta-analysis (NMA), comparing golimumab to adalimumab, certolizumab pegol and etanercept[1].

3.1 GO-AHEAD study

This was a phase III, multicentre, randomised, double-blind, parallel-group, placebo-controlled study designed to evaluate the efficacy and safety of golimumab in adult patients (aged ≥ 18 to ≤ 45 years) with active nr-axSpA[12]. All patients fulfilled the ASAS classification criterion for a positive MRI and at least one spondyloarthritis feature, or human leukocyte antigen subtypes B27 (HLA-B27)-positive and two or more spondyloarthritis features[12]. All patients had chronic back pain of ≥ 3 months duration, and active disease as defined by total back pain assessment of ≥ 40 and a BASDAI score ≥ 4.0 (on a 0–10 VAS). All eligible patients had an inadequate response to, or were intolerant to ≥ 1 NSAIDs during ≥ 30 days of continuous therapy at maximum tolerated dose[12].

The trial was comprised of two parts. In the first part, patients (n = 198) were randomised 1:1 to receive golimumab 50 mg (n = 98) or placebo (n = 100) administered subcutaneously (SC) every 4 weeks for up to 12 weeks. Following

successful completion of part 1, patients were eligible to participate in part 2, which was designed to evaluate the long-term treatment effect and safety of golimumab. All patients in part 2 (n = 189) received open-label golimumab 50 mg SC at week 16, and every 4 weeks thereafter, with the final dose administered at week 48.

The primary endpoint was ASAS20 response (see Glossary) at week 16. For the total nr-axSpA population, a statistically significantly higher proportion of patients in the golimumab arm (71.1%) achieved an ASAS20 response at week 16 compared to placebo (40.0%); $p < 0.0001$. Refer to Table 1.

Similarly, in the objective signs of inflammation (OSI) population (n = 158), which comprised of patients with baseline evidence of sacroiliitis on MRI and/or screening CRP level > upper limit of normal, the magnitude of effect with golimumab was numerically similar to, or greater than, what was observed in the overall study population. A statistically significant increase in the primary endpoint, ASAS20 response rate, was achieved in the golimumab group (76.9%; n = 78) compared to placebo (37.5%; n = 80); $p < 0.0001$. A published abstract reported positive primary and secondary endpoints in part 2, with improvements in disease activity retained in patients who received golimumab and in those who switched from placebo[13].

Table 1. Overview of endpoints from GO-AHEAD study at week 16 for the total nr-axSpA population[1,12].

	Golimumab		Placebo		Treatment difference: golimumab versus placebo
	N		N		
ASAS20 response rate, % (95% CI)	97	71.1	100	40.0	31.2 (17.5 to 43.6) p < 0.0001
ASAS40 response rate, % (95% CI)	97	56.7	100	23.0	33.8 (20.4 to 46.1) p < 0.0001
BASDAI50 response, % (95% CI)	97	57.7	100	30.0	28.0 (14.4 to 40.6) p < 0.0001
ASAS partial remission, % (95% CI)	97	33.0	100	18.0	15.2 (3.2 to 27.1) p < 0.05
Mean CFB SPARCC MRI SI joint score*	74	−5.3	87	−1.0	−4.3 p < 0.0001
Mean CFB ASQoL*	94	−5.5	100	−1.6	−3.5 (−4.7 to −2.2) p < 0.0001
Mean CFB EQ-5D index	94	0.3	100	0.1	0.15 (0.08 to 0.22) p < 0.0001
Mean CFB SF-36 PCS	91	10.6	96	3.4	6.56 (4.28 to 8.83) p < 0.0001
Mean CFB SF-36 MCS	91	6.0	96	1.5	4.24 (1.42 to 7.07) p < 0.05

* decrease from baseline indicates improvement
ASAS: Assessment of SpondyloArthritis international Society; ASAS20: see Glossary; ASAS40: see Glossary; ASQoL: Ankylosing Spondylitis Quality of Life questionnaire; BASDAI: see Glossary; CFB: change from baseline; CI: confidence interval; EQ-5D: EuroQoL-5D health questionnaire; MCS: mental component score; nr-axSpA: non-radiographic axial spondyloarthritis; PCS: physical component score; SF-36: 36-item Short Form health survey; SPARCC MRI SI: Spondyloarthritis Research Consortium of Canada magnetic resonance imaging index for sacroiliac joint inflammation.

3.2 NMA

In the absence of direct comparative data comparing golimumab with adalimumab, certolizumab pegol and etanercept for the treatment of nr-axSpA, the company submission included a systematic literature review and NMA utilising a fixed-effects model. A pairwise meta-analysis was also included to understand between-trial heterogeneity for comparisons informed by more than one study, which included adalimumab and etanercept studies. The systematic review identified all randomised controlled trials and controlled clinical trials that included at least one arm randomised to one of the aforementioned TNF alpha inhibitors in adult patients with severe, active nr-axSpA. A total of six clinical studies were identified, including the GO-AHEAD study[1].

Results of the NMA showed that treatment with TNF alpha inhibitors yielded greater improvements in efficacy outcomes (at the week 12 time point) when compared with placebo in nr-axSpA patients. The company reported a similar efficacy of golimumab compared to adalimumab, certolizumab pegol and etanercept; however, no statistical difference was observed for the majority of outcomes analysed. The only significant

differences claimed by the company concerned golimumab versus etanercept in changes in BASDAI and Bath Ankylosing Spondylitis Functional Index (BASFI [see Glossary]) from baseline, and golimumab versus adalimumab in change in BASFI from baseline. Sensitivity analyses were performed to address the clinical heterogeneity observed across studies with regard to disease duration and severity. The sensitivity analyses supported the conclusions of the main analysis[1].

3.3 Comparative safety

In the GO-AHEAD study, the incidence of treatment-related adverse events (AEs) and serious AEs (SAEs) were comparable between patients treated with golimumab and those treated with placebo in the 16-week double-blind phase (treatment-related AEs: 13.4% golimumab versus 17% placebo; SAEs: 1% golimumab versus 2% placebo); none of the SAEs were considered to be treatment-related[12]. The most common AEs were infections (24.7% golimumab versus 23.0% placebo) and disorders of the gastrointestinal tract (8.2% golimumab versus 15% placebo), nervous system (10.3% golimumab versus 11.0% placebo) and skin and SC tissues (9.3% golimumab versus 6.0% placebo)[6]. Results from the NMA suggested comparable safety profiles for golimumab versus adalimumab and etanercept[1]. The Committee for Medicinal Products for Human Use (CHMP) concluded that the AE profile of golimumab is consistent with that of TNF alpha inhibitors and no new safety signals have been observed for the treatment of nr-axSpA[6].

3.4 AWTTC critique

- Golimumab is currently recommended by NICE for AS. Adalimumab, etanercept and certolizumab pegol are recommended for nr-axSpA, however since the regulatory approval for golimumab was received at a late stage in the process, it was not included by NICE in their appraisal[5].
- In the total nr-axSpA population and OSI population, golimumab was statistically significantly superior in all endpoints versus placebo. In order to address the lack of direct head to head evidence of golimumab versus other TNF alpha inhibitors, the company included a systematic review and NMA (see Section 3.2). They conclude that golimumab was as effective as adalimumab, certolizumab pegol and etanercept; however, the NMA results should be interpreted with caution due to the heterogeneity of the studies with regards to disease duration and severity. In addition, the whole nr-axSpA population was studied, rather than the subgroups with OSI, which are representative of the indication[1].
- No new AEs were identified in the safety data from the GO–AHEAD study. CHMP combined the safety data from this study with AS studies and the overall golimumab safety database, and subsequently concluded that the safety profile of golimumab is in line with other anti-TNF alpha therapies and consistent with previous experience with golimumab. There is a lack of evidence relating to the long term efficacy and safety of golimumab in nr-axSpA patients particularly with regards to how long term treatment should be continued for those in whom there is no disease activity following treatment, or the safety of retreatment after a disease flare; this is evaluated as part of the Risk Management Plan[6].
- Golimumab is injected once every month[2,3] whereas certolizumab pegol is injected every two or four weeks[14], adalimumab is every other week[15] and etanercept can be given once or twice weekly[16-19]. Golimumab[2,3], certolizumab pegol[14], adalimumab[20] and etanercept[21-24] may all be self-injected after correct training in the technique, if their physician determines that it is appropriate and with medical follow-up as necessary. These differences in treatment frequency and administration could impact on the preferences of patients, carers and clinicians.

4.0 SUMMARY OF THE EVIDENCE ON COST-EFFECTIVENESS

4.1 Cost-effectiveness evidence

4.1.1 Context

The company submission includes a cost-minimisation analysis (CMA) comparing golimumab administered SC at a dosage of 50 mg once a month to adalimumab (40 mg administered SC every two weeks), certolizumab pegol (400 mg administered SC at weeks 0, 2, 4 then 400 mg every four weeks thereafter) and etanercept (50 mg administered SC once a week) for the treatment of severe, nr-axSpA in adults in Wales. The company also claimed to have included a different certolizumab pegol regimen (400 mg administered SC at weeks 0, 2, 4 then 200 mg every two weeks thereafter) and a different etanercept regimen (25 mg administered SC twice a week) as comparators; however, they did not present any results for these options. Each TNF alpha inhibitor was considered as an add-on to conventional therapy, where conventional therapy includes NSAIDs and physiotherapy.

A Wales Patient Access Scheme (WPAS) has already been approved. Under this WPAS, the 100 mg dose of golimumab is provided at the equivalent price of the 50 mg dose. This is applied at the point of invoice, when used by NHS Wales in any licensed indication.

The company developed a model using a cost-minimisation approach to estimate the incremental costs over the one year time horizon of the model. The company justified the use of a CMA on an NMA, between golimumab and the other TNF alpha inhibitor comparators used to treat nr-axSpA in Wales, in which clinical equivalence was assumed (see Sections 3.2 and 3.3). The company provided no evidence of equivalence of quality of life outcomes.

The CMA was based on differences in medicine acquisition costs only. No administration or monitoring costs were included in the model. The Simply for Me homecare programme is provided free of charge to all patients registered to receive the service. The cost of this service is fully absorbed by the company and encompasses all elements of the service. The company did not conduct any analyses to address uncertainty.

4.1.2 Results

Results of the base case analysis for the CMA are presented in Table 2. The results show that treatment with golimumab costs £9,156 per patient per year. Adalimumab also costs £9,156 per patient per year. The costs for certolizumab pegol and etanercept were both £9,295 per patient per year.

Table 2. Company-reported results of the base case analysis

	Dose	Annual medicine cost
Golimumab	50 mg via subcutaneous injection once monthly	£9,156
Adalimumab	40 mg via subcutaneous injection once every two weeks	£9,156
Certolizumab pegol	400 mg via subcutaneous injection at week 0, 2, 4, then 400 mg once every four weeks	£9,295
Etanercept	50 mg via subcutaneous injection once weekly	£9,295

The base case model is for 50 mg; however, it is noted that under the current WPAS the 100 mg dose of golimumab is provided at the same price as the 50 mg. Given that

the CMA is based on differences in medicine acquisition costs only, it can be assumed that the result is the same for 100 mg.

The company did not conduct any analyses to address uncertainty.

4.1.3 AWTTC critique

- The reliability of the company's CMA is dependent on the extent to which golimumab is considered therapeutically equivalent to the comparator therapies with respect to all dimensions of health outcomes (benefits and harms) and any relevant issues concerning patient preference that may impinge on these outcomes. The clinical equivalence is based on the findings of the NMA and equivalence trials have not been undertaken on this indication; therefore, the case for CMA has not been proven.
- The assumption of equivalence used for the CMA is based on NMA outcomes where there were no statistically significant differences in efficacy outcomes between golimumab and the other TNF alpha inhibitors. Despite the overlapping credible intervals (Crls) around the mean treatment effects in the NMA, these are wide. In addition, the NMA did not include any quality of life measures and some of the efficacy outcomes (BASDAI, BASFI) demonstrated superiority of golimumab versus etanercept and adalimumab. Hence, equivalence is not demonstrated.
- The network of evidence in the NMA was relatively small and the studies included in the network do not have particularly large sample sizes which limits the statistical power to detect statistically meaningful differences between treatment effects. Furthermore, differences in patient populations in the studies included in the NMA included age, disease duration, baseline CRP values and biologic naïve status.
- There is a precedent for the use of cost utility analysis in nr-axSpA as previous models submitted to NICE have used BASDAI and BASFI as outcome measures[25].
- The company did not include administration and monitoring costs in the model despite different dosing regimens associated with the golimumab and the TNF alpha inhibitor comparators. The company assumed (i) that patients generally self-administer at home hence administration costs for the subcutaneous injectable treatments are zero; and (ii) the frequency of monitoring is not directly impacted by the frequency of administration hence monitoring costs do not differ between treatment regimens.
- The time horizon of one year does not reflect the much longer duration of treatment with TNF alpha inhibitors for adult patients with severe, nr-axSpA.
- Although not specifically stated by the company, the annual medicine acquisition costs estimated in the model are post-first year treatment costs. The first year treatment costs for certolizumab pegol are much lower (£6,435) due to an agreed PAS in which the manufacturer provides the first twelve weeks of certolizumab pegol free of charge, equivalent to ten vials. Without the PAS, the first year treatment costs would be £10,010.
- The company did not include any sensitivity analyses.

4.2 Review of published evidence on cost-effectiveness

Standard literature searches conducted by AWTTC did not identify any cost-effectiveness analyses of golimumab for the treatment of adults with severe, nr-axSpA.

5.0 SUMMARY OF EVIDENCE ON BUDGET IMPACT

5.1 Budget impact evidence

5.1.1 Context and methods

The company presented the budget impact assessment for the use of golimumab in adult patients for the treatment of severe, nr-axSpA. The company estimated the

population of Wales from StatsWales, assuming an annual growth rate of 0.3%[26]. They assumed a 0.15% prevalence rate for nr-axSpA, based on estimates from NICE[25]. They assumed an incidence rate of 0.00023% per year, also based on estimates from NICE[27]. Using an annual mortality rate of 1.61%[28], they estimated the net number of patients treated for nr-axSpA in Wales to be 4,599 in year 1, increasing to 4,655 in year 5.

The company estimated that 20% of patients with nr-axSpA are eligible for treatment with TNF alpha inhibitors[29]. The estimated uptake of golimumab was based on the company's market research data and predictions, increasing from 3% in year 1 to 16% in year 5. The company also assumed a discontinuation rate of 5% per year, based on NICE TA 383[5].

As per the CMA, only medicine acquisition costs were included in the estimation of the budget impact. The annual drug acquisition costs were the same as those used in the CMA.

The company does not estimate which TNF alpha inhibitors would be displaced by golimumab. Instead, the company estimates the net costs for each comparison, assuming that each comparator TNF alpha inhibitor would be fully displaced according to estimated market share of golimumab in each comparison.

5.1.2 Results

The company estimates the acquisition costs of treatment with golimumab 50 mg or 100 mg to be £9,156 per patient per year (including the WPAS price). This compares to £9,156 for adalimumab and £9,295 for both certolizumab pegol and etanercept. The estimated number of patients and the associated costs as described by the company in their budget impact analysis are summarised in Table 3.

The comparison in which golimumab fully displaces adalimumab results in zero net cost each year. The comparison in which golimumab fully displaces certolizumab pegol results in a net cost of −£3,763 in year 1 increasing to −£19,789 in year 5. For the comparison in which golimumab fully displaces etanercept, the net cost savings are similar to the comparison with certolizumab pegol.

Table 3. Company-reported net costs associated with the use of golimumab for the treatment of adults with severe, nr-axSpA

	Year 1	Year 2	Year 3	Year 4	Year 5
Patients with nr-axSpA	4,666	4,680	4,694	4,709	4,723
New patients diagnosed	8	8	8	8	8
Mortality rate	1.61%	1.61%	1.61%	1.61%	1.61%
Net number of patients with nr-axSpA	4,599	4,613	4,627	4,642	4,655
Eligible patient rate as per license	20%	20%	20%	20%	20%
Number of patients likely to be prescribed golimumab	3%	6%	8%	12%	16%
Discontinuation rate	5%	5%	5%	5%	5%
Number of patients likely to be prescribed new medicine	27	54	72	107	142
Net costs					
Overall net costs vs adalimumab	£0	£0	£0	£0	£0
Overall net costs vs certolizumab pegol	−£3,763	−£7,525	−£10,034	−£14,911	−£19,789
Overall net cost vs etanercept	−£3,763	−£7,525	-£10,034	−£14,911	−£19,789

The company did not conduct any scenario analyses to assess the impact of varying input parameters on the overall budget impact.

5.1.3 AWTTC critique

- The cost estimates used in the budget impact are derived from the company's CMA; therefore, the limitations and uncertainties associated with the CMA also apply to the budget impact analysis.
- Due to the lack of epidemiological data for nr-axSpA in Wales, the estimation of the number of patients is based on assumptions and data drawn from published studies. Consequently, there is uncertainty about the number of adult patients eligible for treatment with golimumab in Wales. The estimate appears to include children and adolescents.
- The company did not conduct any scenario analyses on alternative estimates of the number of adults with severe nr-axSpA.
- The company did not estimate which TNF alpha inhibitors would be displaced by golimumab. Instead, they estimated the budget impact for different comparisons in which each of the comparator TNF alpha inhibitors was completely displaced.
- In the comparison with certolizumab pegol, the company did not take into account its WPAS in which the manufacturer provides the first twelve weeks of certolizumab pegol free of charge (equivalent to ten vials). This would impact the costs in year 1.
- The company did not take into account the cumulative costs for patients carrying on treatment beyond the first year.

5.2 Comparative unit costs

Table 4 includes example comparative annual acquisition costs of golimumab and alternative TNF alpha inhibitors, based on current British National Formulary (BNF) list prices.

Table 4. Examples of annual acquisition costs per patient of TNF alpha inhibitors for the treatment of severe, nr-axSpA in adult patients

Regimens	Example dose	Cost per patient per year
Golimumab (Simponi®) 50 mg and 100 mg prefilled injection	50 mg or 100 mg once monthly on the same day each month	£9,156 (£18,311 for 100 mg if WPAS not taken into account)
Adalimumab (Humira®) 40 mg prefilled injection	40 mg every two weeks	£9,156
Certolizumab pegol (Cimzia®) 200 mg prefilled injection	400 mg every 2 weeks for 3 doses, then 200 mg every 2 weeks or 400 mg every 4 weeks	£10,010 first year (400 mg dose) £10,368 first year (200 mg dose) £9,295 subsequent years
Etanercept (Enbrel®) 25 mg and 50 mg prefilled injection	25 mg twice weekly or 50 mg once weekly	£9,295
Costs based on BNF prices, April 2016[30] Costs of administration and monitoring are not included. This table does not imply therapeutic equivalence of medicines at the stated doses.		

6.0 ADDITIONAL INFORMATION

6.1 Prescribing and supply

AWTTC is of the opinion that, if recommended, golimumab (Simponi®) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.

The company anticipate that golimumab (Simponi®) may be supplied by a home healthcare provider.

6.2 Ongoing studies

The company submission states that there are no ongoing studies from which additional evidence is likely to be available within the next 6–12 months.

6.3 AWMSG review

This assessment report will be considered for review three years from the date of the Final Appraisal Recommendation.

6.4 Evidence search

Date of evidence search: 18 March 2016.
Date range of evidence search: No date limits were applied to database searches.

GLOSSARY

ASAS20 response
An improvement of ≥ 20% and an absolute improvement of ≥ 10 units (range 0-100) from baseline in at least 3 of the following 4 domains:

- Patient global assessment
- Pain (total back pain)
- Function (represented by BASFI)
- Inflammation (average of the last 2 questions of the BASDAI concerning morning stiffness)

and absence of deterioration (≥ 20% and an absolute change of ≥ 10 units) in the potential remaining domain[6].

ASAS40 response
An improvement of ≥ 40% and an absolute improvement of ≥ 20 units from baseline in at least 3 of the 4 domains identified in ASAS20, with no deterioration in the remaining domain[31].

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
A validated self-assessment instrument which consists of six 10-unit horizontal visual analogue scales to measure severity of fatigue, spinal and peripheral joint pain and swelling, enthesitis, and morning stiffness (both severity and duration, respectively). The final BASDAI score ranges from 0 to 10, with lower scores indicating lower disease activity[6].

Bath Ankylosing Spondylitis Functional Index (BASFI)
A self-assessment instrument designed to define and monitor functional ability. BASFI consists of ten questions, eight of which relate to functional anatomy of the patient and two of which assess the patient's ability to cope with everyday life. Each question is answered on a 0 to 10 visual analogue scale and the mean of which gives the BASFI score[6].

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